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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,281	08/23/2006	Dana Rae Benesh	X-16090	2288

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
06/03/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/598,281	BENESH ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/23/2006; 9/28/2007; 5/20/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election **without specifying** traverse of a single species in the reply filed on 5/20/2011 is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. In particular, Applicant elected the species of Example 1. The elected species reads upon claims 17 and 27.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 17 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.**

5. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claims 17 and 27 compounds, including the elected compound species, or **solvates** thereof, as well as compositions comprising the elected compound species or **solvates** thereof..

6. The MPEP §2163 states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. In the case of chemical entities, Applicant's attention is

further directed to *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), which holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. Furthermore, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. Although the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus, if the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. While the MPEP does not define what constitutes a sufficient number of representative species, the courts have indicated what does not constitute a representative number of species to adequately describe a broad generic. For example, in *In re Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

7. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office (PTO) Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.I "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention" *Enzo Biochem, Inc. v.*

Gen-Probe Inc., 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106). Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP §2163. However, if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP §2163.

8. The instant claims are drawn to a compound of formula (I), which includes Applicant's elected compound species and **solvates** thereof.

9. Level of skill and knowledge in the art: The level of skill in the art is high.

10. Partial structure: The elected species has been disclosed. However, as to the claimed **solvates** of the elected compound species, no specific examples are given that would demonstrate possession of or put the public in possession of the claimed **solvates** of the elected compound species.

11. Physical and/or chemical properties/Functional characteristics: The elected species and **solvates** thereof, are compounds which are allegedly useful as opioid receptor antagonists in the treatment of obesity. It is known in the art that **solvates** can be defined as solid adducts containing the parent compound and solvent, wherein the solvent is incorporated into the crystal lattice of the parent substance. When the solvent is water, as is often the case for pharmaceutical systems, the material is termed a hydrate. Accordingly, the term **solvate** encompasses **hydrates** which can be defined as molecular complexes that have water molecules incorporated into their

crystal lattice and pharmaceutical hydrates are co-crystals of water and drug molecules. However, neither term is explicitly defined by the Specification (for example, as to **hydrate**s, by precisely defining the number of water molecules per drug molecule and other descriptive characteristics) in such a way as to demonstrate that the inventor had possession of the claimed **solvate**s (including **hydrate**s) of the elected compound species.

12. Predictability of the Art: It is generally accepted in the art that formation of a particular solvate or hydrate for a given compound or series of compounds is unpredictable.

13. As stated by *Han* (Advances in Characterization of Pharmaceutical Hydrates. Trends in Bio/Pharmaceutical Industry, pages 25-29. March, 2006) "[t]he physiochemical, processing, mechanical and compaction behavior of pharmaceutical hydrates can be different from those of the corresponding anhydrous phases" and that "[a]mong the different solid states of drugs, hydrate formation is one of the commonly encountered phenomena and may cause as many challenges as different polymorphs may cause" (Page 25, Paragraph 1). Furthermore, *Han* states that "no single technique can provide enough information for the understanding of hydrate systems. A comprehensive study of hydrate should include: structure information, such as powder XRD and crystal structure, solid state NMR; thermal properties such as DSC, TGA data; vibrational spectroscopy profiles such as Infrared Spectroscopy (IR), Fourier Transform Infrared spectroscopy (FTIR) and Raman Spectroscopy; and hydroscopicity such as moisture absorption/desorption. In addition, the phase diagram of the hydrate system is essential information for determining the drug processing and storage conditions" (Page 28, Paragraph 2).

14. Furthermore, *Vippagunta et al* (Adv Drug Deliv Rev 48:3-26, 2001) specifically state that "predicting the formation of solvates or hydrates of a compound and the number of molecules of

water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of related compounds" (Page 18, Section 3.4).

15. Method of making the claimed invention: Although the Specification provides a method for making the elected compound species, no method for making the **solvates** (including **hydrates**) encompassed by the claims has been disclosed.

16. Summary: In the instant case, Applicant has not disclosed the structure, formula, chemical name, or physical properties of the numerous potential **solvates** (including **hydrates**) (i.e., monohydrates, dihydrates... decahydrates, etc) of the elected species. Although some functional characteristics are disclosed or would be known to a person of ordinary skill in the art, in the absence of a disclosed structure, there can be no correlation between the function and structure of the claimed **solvates** (including **hydrates**) in the instant application.

17. However, the MPEP states that written description for a genus (for example, the claimed **solvates** (including **hydrates**) of the elected compound species) can be achieved by a representative number of species within a broad generic. It is unquestionable that the claim(s) are broad and generic with respect to all possible compounds encompassed by the claims: the possible structural variations are limitless to any **solvate** (including **hydrates**) of the elected compound species. In the instant case, however, the Specification does not disclose a sufficient variety of species to reflect this variance in the genus. While having written description of the elected compound and compounds identified in the Specification tables and/or examples, the Specification does not provide sufficient descriptive support for the myriad of compounds

embraced by the claims such as, for example, **solvates** (including **hydrates**) of the elected species.

18. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1628